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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,775	01/04/2001	David J. Grainger	295.009US3	6351
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Rochelle K Seide Baker Botts LLP 30 Rockefeller Plaza New York, NY 10112			EXAMINER KIM, JENNIFER M	
			ART UNIT 1617	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/754,775	<b>Applicant(s)</b> GRAINGER ET AL.	
	<b>Examiner</b> Jennifer Kim	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 173-194, 196-203, 205-211, 231 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 173-194, 196-203, 205-211, 231 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

The amendment filed June 01, 2007 have been received and entered into the application.

### Action Summary

The rejection of claims 173-181, 183 and 208 under 35 U.S.C. 112, first paragraph (enablement) is hereby expressly **withdrawn** in view of Applicants' amendment.

The rejection of claim 231 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claim 231 under 35 U.S.C. 112, second paragraph, is hereby expressly **withdrawn** in view of Applicants' persuasive argument and supporting enclosures that the phrase "small vessel disease" is understood and conventionally used in the art and therefore the phrase is definite.

The rejection of claims 173, 174, 178-183, 186-191, 196-201, 205-208, 210, 211 and 231 under 35 U.S.C. 102(b) as being anticipated by Nuovo et al. (1989) is hereby expressly **withdrawn** in view of Applicant's persuasive argument.

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The rejection of claims 175-177, 184, 185, 192-194, 202, 203 and 209 under 35 U.S.C. 103(a) as being unpatentable over Nuovo et al. (1989) is being expressly **withdrawn** in view of Applicant's persuasive argument.

The Double Patenting rejection of claims 173-194, 196-203, 205-211 and 231 provisionally under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 153-173 of copending Application No. 10/729,056 is being **maintained** for the reasons stated in the previous Office Action and the rejection is repeated in this Office Action.

The Double Patenting rejection of claims 173-194, 196-203, 205-211 and 231 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,410,587B1 is hereby expressly withdrawn in view of Applicants' persuasive argument that the R9 in the compound of formula (VI) in the '587 patent does not include ethyl or chloroethyl. However, this rejection is reformulated in this Office Action for the claims 200-201, 205 and 206. (see rejection below).

The rejection of claims 173-181, 205-211 and 231 under 35 U.S.C. 103(a) as being unpatentable over Sawada et al. (Pharmacometrics, 1992) is being **maintained** for the reasons stated in the previous Office Action and the rejection is repeated in this Office Action.

The rejection of claims 182-194, 196-203, 205, 206 under 35 U.S.C. 103(a) as being unpatentable over Warri (Dissertation Abstracts International, 1993) is hereby expressly **withdrawn** in view of Applicants' persuasive argument.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 231 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is directed to a genus of **small vessel disease** which encompasses a vast array of diseases that are associated with small vessels. The instant specification does not describe the specific requisite characteristic of the disease in order to determine exactly which are qualified as “small” vessel disease. Any vessels in the body are somewhat “small” and within the physiology of the human body. This instant specification therefore does not provide a basis for one of skill in the art to envision the physical/functional characteristics of such a vessels involved in the “small vessel disease”. Given this lack of description of sufficiently representative species encompasses by the genus of the claim the specification fails to sufficiently describe the claimed invention is such full, clear, concise, and exact term

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that a skilled artisan would recognize that Applicants were in possession of the claimed invention.

Claims 200, 201, 203, 205 and 206 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 200, 201, 203, 205 and 206 are drawn to a method of increasing the level of TGF-beta in a mammal at risk of or afflicted with a cardiovascular or vascular indication characterized by a decreased lumen vessel diameter, comprising administering to a mammal at risk of or afflicted with said cardiovascular or vascular indication an effective amount of **an agent** that directly or indirectly elevates the level of active TGF-beta in said mammal, wherein the agent has characteristics of reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination thereof. The claim thus encompass a broad genus of **an agent** that directly or indirectly elevates the level of active TGF-beta in said mammal, wherein the agent which must have the property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination thereof.

The instant specification does not describe or exemplify **all agents** which must have the property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination thereof.

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This instant specification, therefore, does not provide a basis for one of skill in the art to envision any one of such agents. The premise for the limitation **agents** which must have the property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination thereof appears to be derived from the specific formula I of the instant specification. The specification does not however, indicate why one should assume based on **this observation of the specific structural formula, that any agent** would have the property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen. Therefore there is no basis to predict **any agent** having a particular property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination thereof.

Give the broad of genus of **an agent** having the property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen encompassed by the rejected claim, and given the lack of a basis provided by instant specification or prior art to envision such **agents** that are necessary capable of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination thereof, one of skill in the art would not have been able to envision a sufficient number of an agents possessing the property of having reduced estrogenic activity relative to tamoxifen, reduced DNA adduct formation relative to tamoxifen or any combination of characteristics thereof to describe broadly claimed genus. Therefore, one of skill in the art would reasonably have concluded Applicants' were not in possession of the claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 173-194, 196-203, 205-211 and 231 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 153-173 of copending Application No. 10/729,056. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application teaches an aspect of the claims in the instant application. For example, the method of claim 173 in the present application is similar to the method claimed in claim 153-173 utilizing same biological pathway comprising increasing the level of TGF-beta encompassing utilized same active agents. The copending application teaches the mechanisms of action or biological pathways presently claimed by Applicants and renders obvious the diseased claimed in the instant application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 200-201, 205 and 206 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,410,587B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent disclose and teach an aspect of the claims in the present application. Both sets of claims encompass administration of the same active agent (a structural analog of tamoxifen) to the same subject (a mammal at risk of or afflicted with a cardiovascular or vascular indication). Therefore, any mechanism of action of increasing the level of TGF-beta is obvious upon administration of the same active agent to the same subject encompasses by the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 173-182, 186-193, 196-201, 203, 205-211 and 231 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al. (WO 94/09764) evidenced by Schilling (1975).

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Ito et al. teach that use of Nonsteroidal anti-estrogen compound such as toremifene is effective remedy for the treatment of blood vessels disease such as angitis. (page 1, first two paragraphs, page 3, lines 5-25).

Schilling teaches that angitis mainly effect small to average size arteries. Schilling reference is employed as an extrinsic evidence to show that angitis is a small vessel disease.

Claims 200, 205 and 206 are rejected under 35 U.S.C. 102(b) as being anticipated by Connolly et al. (U.S. Patent No. 5,250,561).

Connolly et al. teach that tetrahydroindazole compounds are useful in treatment or prevention of hypercholesterolemia and atherosclerosis.

The instantly claimed "an agent" to be employed is encompassed by this teaching because the tetrahydroindazole compound disclosed by Connolly et al. has no estrogenic activity which meets the requirement of the agent having reduced estrogenic activity relative to tamoxifen. Further, the mechanism of action of increasing the level of TGF-beta gives the pharmacological effect does not alter the fact that the compound (an agent having property of **reduced** estrogenic activity relative to tamoxifen) has been previously used to obtain the same pharmacological effects (atherosclerosis) which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 173-181, 205-211 and 231 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawada et al. (Pharmacometrics, 1992).

Sawada et al. teach the administration of toremifene citrate (NK622) in 0.1 mg/kg or more including 10mg/kg (cytostatic dose) to female rats showed decrease in total cholesterol in rats.

Sawada et al. do not teach a mammal at risk of or afflicted with cardiovascular or vascular indication (atherosclerosis) or mechanism of increasing the level of TGF-beta to decrease lesion formation or inhibition of lipid accumulation, and dosage formulation and the employment of analogs set forth in claim 176.

It would have been obvious to one of ordinary skill in the art to employ toremifene citrate (NK622) in 0.1 mg/kg or more including 10mg/kg (cytostatic dose) to a mammal at risk or afflicted with cardiovascular or vascular indication such as atherosclerosis. One would have been motivated to employ toremifene citrate (NK622) in 0.1 mg/kg or more including 10mg/kg (cytostatic dose) to a mammal at risk or afflicted with cardiovascular or vascular indication such as atherosclerosis because Sawada et al. teach the administration of toremifene citrate (NK622) in 0.1 mg/kg or more including 10mg/kg (cytostatic dose) to female rats showed decrease in total cholesterol in rats.

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One would be further motivated to make such a modification in order to achieve an expected benefit of lowering total cholesterol level in a mammal suffering from atherosclerosis. The pharmaceutical forms, e.g., sustained release, immediate release etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Further, the reference discloses compounds which have a viable utility and are homolog, isomers or close structural analogs of the claimed compounds. The claimed compounds are so closely related structurally to the homologous; isomeric or analogous compounds of the reference as to be structurally obvious therefrom in the absence of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that compounds so closely related structurally would have the same or essentially the same properties. That applicant may have determined a mechanism by which the active ingredient gives increasing the level of TGF-beta to decrease lesion formation or inhibition of lipid accumulation does not alter the fact that the compound has been previously used to obtain the same pharmacological effects (lowering total cholesterol) which would result from the claimed method upon the administration of same active agent in a same amount to the mammal in need thereof. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

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Claims 183-185, 194 and 202 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (WO 94/09764).

Ito et al. teach that use of Nonsteroidal anti-estrogen compound such as toremifene is effective remedy for the treatment of blood vessels disease such as angitis (small vessel disease). (page 1, first two paragraphs).

Ito et al do not teach specific tamoxifen analogs such as idoxifene and doroloxifene and the subjects having medical conditions such as diabetic retinopathy, diabetes, or diabetic retinopathy set forth in claims 183-185.

It would have been obvious to one of ordinary skill in the art employ toremifene and its analogs such as idoxifene or doroloxifene for the treatment of angitis (small vessel disease) because Ito et al. teach that toremifene and its discloses analogs of toremifene which have a viable utility of treating angitis and because toremifene is structural analogs of idoxifene or doroloxifene. The claimed compounds are so closely related structurally to the homologous; isomeric or analogous compounds of the reference as to be structurally obvious therefrom in the absence of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that compounds so closely related structurally would have the same or essentially the same properties.

With regard to the patient suffering from angitis to the secondary medical conditions such as diabetes, diabetic retinopathy, or diabetic retinopathy, it would have been obvious to one of ordinary skill in the art to employ toremifene and its structural analogs for the treatment of patient having angitis regardless of their secondary medical

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condition in order achieve an expected benefit of effectively treating primary medication condition of angitis. With regard to mechanism of action of increasing TGF-beta in a patients afflicted with angitis is obvious because a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Claims 173-194 and 196-203 and 205-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (U.S. Patent No. 5,445,941).

Yang teaches that antiestrogen such as toremifene is useful for treating osteoporosis because it induce human fetal fibroblast to secrete TGFb in absence of estrogen receptor. (column 2, under antiestrogens, column 4, lines 6-10). Yang teaches that elevated serum levels of low density lipoproteins correlate with increased incidence of coronary artery disease, atherosclerosis and myocardial infarction are noted in women with osteoporosis.

It would have been obvious to one of ordinary skill in the art that the osteoporosis patients disclosed by Yang et al. is at risk of cardiovascular or vascular indication characterized by a decreased lumen diameter because a condition such as osteoporosis correlates with increased incidence of coronary artery disease, atherosclerosis and myocardial infarction as taught by Yang et al. With regard to

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increasing the level of TGF-beta in the osteoporosis patients disclosed by Yang et al. is obvious because Yang et al. teach that toremifene induced secretion of TGB-beta in the absence of estrogen receptor. One of ordinary skill in the art would be motivated to employ toremifene to a patient having osteoporosis disclosed by Yang et al. regardless of their secondary conditions such as diabetes, diabetic retinopathy, or diabetic retinopathy, in order to achieve an expected benefit of inducing secretion of TGF-beta in treating osteoporosis without the estrogen receptor. With regard to employment of idoxifene or doroloxifene are deemed obvious because the cited reference discloses compounds which have a viable utility and toremifene is structural analogs of the claimed compounds. The claimed compounds are so closely related structurally to the homologous; isomeric or analogous compounds of the reference as to be structurally obvious therefrom in the absence of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that compounds so closely related structurally would have the same or essentially the same properties.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

***Response to Arguments***

Applicants' arguments filed June 1, 2007 have been fully considered but they are not persuasive. Applicants argue that the phrase "small vessel disease is understood and conventionally used in the art, and the specification discloses that small vessel disease includes silent myocardial infarction, vascular insufficiency in the limbs, peripheral neuropathy and retinopathy and therefore the claims complies with the written description requirement. This is not persuasive because the issue is whether the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, **had possession** of the claimed invention. In this case, Applicants disclosed **few species** of small vessel disease in the instant specification do not provide sufficient information so that the skilled artisan will be enabling to envision the claimed genus of small vessel disease. There is substantial variability among species having different unrelated etiology. One of skill in the art would not recognize from the disclosure of those divergent species that the applicants were in **possession** of the genus which comprises the **broad genus of small vessel disease**.

Applicants argue that there is insufficient suggestion or motivation to modify Sawada to reach the present invention because the decrease in cholesterol is part of a general toxic syndrome arising from higher than appropriate dosage of toremifene which corresponds with suppressed weight gain and a drop in feed consumption. This is not persuasive because instant claims are drawn to "cytostatic dose" of a therapeutic agent (i.e. claim 173) and "effective amount" of treating "arteriosclerosis . . ." (i.e. claim 231).

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Therefore, the teaching of Sawada that the dose administered to “decrease in cholesterol” encompasses the “cytostatic dose” and “effective amount” to treat arteriosclerosis. It is noted that Sawada’s “higher than appropriate dosage of toremifene” asserted by Applicants’ still reads within the claimed dosage limitation as “cytostatic” and “effective”. Applicants argue that based upon the disclosure of Sawada, it is unclear whether the reduction in total cholesterol is due to the action of toremifene on TGFb levels, whether it is due to the toxicity of toremifene, or if it is due to the decrease in feed consumption. This is not persuasive because the teaching of Sawada is clear that the effect of decrease in total cholesterol is resulted of orally administered NK622 (toremifene). Applicants’ attention is drawn to second paragraph of abstract of Sawada where it states “This experiment yielded the following results... showed decreases in total cholesterol, phospholipid and total protein values in rats receiving 0.1mg/kg or more...”.

Any rejection of record not addressed herein is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kim  
Patent Examiner  
Art Unit 1617

Jmk  
August 18, 2007